REMARKS/ARGUMENTS

Claim objection

Claim 23 has been objected to because of an informality. Claim 23 has been amended to correct the informality.

Claim rejections – 35 USC 112 – written description

The Examiner has rejected Claim 23 as failing to comply with the written description requirement.

Applicants have amended Claim 23 to comply with the written description requirement. As the Examiner has pointed out, the specification describes induction of apomixis through transformation with a CHD-down regulation (CHD-DR) cassette. The claim has been amended to be commensurate with the description and the rejection is obviated.

Claim 23 has been further amended to reflect the fact that apomixis as claimed relates to whole plants, not to plant cells.

New claims 48-51 are directed to aspects of the same subject matter and are supported by the specification, for example at page 4, line 30, through page 5, line 2; and at page 6, lines 5 through 14.

Rejection under 35 USC 112 – Enablement

The Examiner has rejected Claim 23 as failing to comply with the enablement requirement. The Examiner states that "the downregulation of the expression of a particular gene in plants is unpredictable, as the ability of a construct to suppress gene expression depends on multiple variables which include but are not limited to the type of components used and their arrangement within the construct, the degree of homology between the construct components and the gene to be downregulated, the presence or absence of other homologous genes in the genome of the target cell, and the level at which the expression of the gene is regulated." The Examiner further states

that in order to practice the claimed invention, one of skill in the art would have to engage in "undue experimentation."

Applicants respectfully traverse the rejection.

The Federal Circuit has repeatedly stated that enablement is not precluded by the necessity for some experimentation, so long as the experimentation needed to practice the invention is not undue, and that a considerable amount of experimentation is permissible if it is merely routine or if the specification provides a reasonable amount of guidance as to how the experimentation should proceed. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Further, "[t]he fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." MPEP 2164.01, citing *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). In the biotechnological arts, screening of numerous constructs and transformants is routine and typical.

Applicants note the Examiner's citation of Sandler et al. (1988) and van der Krol et al. (1990) with regard to the predictability of downregulation. Applicants note that both references do report successful downregulation of the target genes and respectfully submit that identification of the most effective constructs is within the scope of routine experimentation. Further, Applicants respectfully point out that the priority date of the pending application is December 2000, ten years after the van der Krol reference published, and submit that the art had advanced considerably between 1990 and 2000. Applicants provide the following pre-filing-date examples of successful downregulation by antisense, sense suppression, ribozyme, and dominant negative inhibition, respectively:

> Muller et al., Maize Genetics Cooperative Newsletter 70:25 (1996). Chalcone synthase antisense expression in transgenic maize leads to white pollen phenotype.

Terada et al., Plant and Cell Physiology 41(7):881-888 (July 2000). Antisense waxy genes with highly active promoters effectively suppress Waxy gene expression in transgenic rice.

Vailhe et al., Journal of the Science of Food and Agriculture 76(4):505-514 (1998). Effect of downregulation of cinnamyl alcohol dehydrogenase on cell wall composition and on degradability of tobacco stems. (antisense)

Tsai et al., Plant Physiology 117(1):101-112 (1998). Suppression of O-methyltransferase gene by homologous sense transgene in quaking aspen causes red-brown wood phenotypes.

Merlo et al., Plant Cell 10(10):1603-1621 (1998). Ribozymes targeted to stearoyl-ACP delta 9 desaturase mRNA produce heritable increases of stearic acid in transgenic maize leaves.

Unger et al., Plant Cell 5(8):831-841 (1993). Dominant negative mutants of Opaque2 suppress transactivation of a 22kD zein promoter by Opaque2 in maize endosperm cells.

Other examples are cited in the specification; see especially page 18, line 28, through page 19, line 16.

The Examiner cites Waterhouse et al. (1999) for the teaching that "antisense suppression of gene expression requires a high degree of sequence homology (>75%) between the endogenous sequence and the antisense transgene to be effective." Applicants respectfully respond that the findings of Waterhouse et al. may be seen as providing guidance for the preparation and use of antisense constructs, effectively reducing the number of potential constructs to be tested and the need for experimentation.

The Examiner cites Temple et al. who reported that reduced transcript levels of certain glutamine synthetase 1 genes did not result in reduced glutamine synthetase activity, suggesting both transcriptional and translational/post-translational control of

expression. The Applicants respectfully respond that the conclusion that glutamine synthetase synthesis is unaffected by down-regulation of a member of a multigene family encoding glutamine synthetase is not determinative of efficacy of the constructs disclosed in the present application.

Finally, the Examiner cites Eissenberg regarding the identification of numerous chromo-domain-containing proteins and states that insufficient guidance is provided as to which CHD gene to downregulate in plants. The claims have been amended and the objection is obviated.

In view of the above amendments and remarks, Applicants submit that all grounds for rejection have been overcome. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Respectfully submitted,

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